

REMARKS

Claims 23-52 are presently pending in the case. Claims 25 and 27 have been withdrawn from consideration until such time as they depend from an indicated allowable generic claim. Claims 23 and 42 have been amended. The amendments are supported by the specification as originally filed.

Reconsideration of the present case in view of the above amendments and the remarks herein is requested.

Claim rejections under 35 USC §102

The Examiner rejected claims 23, 24, 26 and 28-52 under 35 USC §102(e) as being anticipated by U.S. Patent 5,735,263 to Rubsamen et al (hereinafter Rubsamen et al). The rejection is traversed.

Rubsamen et al does not anticipate independent claim 23. For a rejection under 35 USC §102 to be proper, the reference relied upon must disclose each and every element of the claimed invention. Non-disclosure of a single element, feature or limitation of the claim negates anticipation. Claim 23 is to a device comprising, inter alia, a flow restrictor for limiting the inspiratory flow of an aerosolized active agent formulation to a human patient to less than 17 liters per minute. This positively recited feature is not disclosed by Rubsamen et al. Rubsamen et al does not disclose a flow restrictor for limiting the flow of an aerosolized active agent to less than 17 liter per minute. Instead, Rubsamen et al discloses a inhalation device where the inspiratory flow rate is not limited. As can be seen in Figures 5-9 and in column 5 lines 50-55 of Rubsamen et al, flow rates much higher than 17 liters per minute can easily be achieved by a patient using the device. Since Rubsamen et al does not disclose each and every feature set forth in claim 23, it does not anticipate the claim.

The Examiner refers to recitations within Rubsamen et al, such as column 5 lines 50-55, that are purported to support the Examiner's position that Rubsamen et al teaches limiting the flow rate. However, the recitations do not in actuality teach that which is claimed by Applicant in claim 23. Rubsamen et al is merely referring to the flow rates at which the aerosolized formulation may be released into the inhalation stream. Thus, Rubsamen et al does not disclose or teach all that is claimed by Applicant in claim 23. In addition, the Examiner refers to a solenoid valve (9) in Rubsamen et al. However, Rubsamen et al does not disclose that the solenoid valve (9) limits the flow rate as recited in Applicant's claim 23. The valve (9) in Rubsamen et al instead is opened to allow a formulation to be aerosolized when a patient's inhalation flow rate is measured to have reached a predetermined amount (see column 24 line 22 though column 25 line 33). Rubsamen et al does not disclose a restrictor that restricts flow. Using the Rubsamen et al device, a patient may inhale at flow rates significantly higher than 17 liters per minutes (see column 5 lines 50-55).

Applicant requests withdrawal of the rejection of claim 23 under 35 U.S.C. §102(e). In addition, Applicant requests withdrawal of the rejection of claims 24-32 which depend from claim 23 and are not anticipated by Rubsamen et al for at least the same reasons as claim 23.

Independent claim 33 is also not anticipated by Rubsamen et al. Claim 33 is to a device for delivering an aerosolized active agent to the lungs of a human patient, wherein said device is adapted to deliver an aerosolized active agent formulation at an inspiratory flow rate limited to a rate less than 17 liters per minute. Rubsamen et al does not disclose a device that limits inspiratory flow rate to a rate less than 17 liters per minute. Therefore, Rubsamen et al does not anticipate claim 33.

Applicant requests withdrawal of the rejection of claim 33 under 35 U.S.C. §102(e). In addition, Applicant requests withdrawal of the rejection of claims 34-37 which depend from claim 33 and are not anticipated by Rubsamen et al for at least the same reasons as claim 33.

Rubsamen et al does not anticipate independent claim 38, either. Claim 38 is to a device comprising, inter alia, a flow restrictor to restrict an inspiratory flow rate of an aerosolized formulation to less than 17 liters per minute. Rubsamen et al does not anticipate claim 38 in that it does not disclose a flow restrictor to restrict an inspiratory flow rate of an aerosolized formulation to less than 17 liters per minute.

Applicant requests withdrawal of the rejection of claim 38 under 35 U.S.C. §102(e). In addition, Applicant requests withdrawal of the rejection of claims 39-41 which depend from claim 38 and are not anticipated by Rubsamen et al for at least the same reasons as claim 38.

Furthermore, independent claim 42 is also not anticipated by Rubsamen et al. Claim 42 is to a device for delivering an aerosolized active agent to the lungs of a human patient, wherein said device comprises one or more orifices sized so that an aerosolized active agent formulation may be delivered at an inspiratory flow rate that is limited to a rate of less than 17 liters per minute. Rubsamen et al does not disclose orifices sized so that an aerosolized active agent formulation may be delivered at an inspiratory flow rate of less than 17 liters per minute. Thus, Rubsamen et al does not anticipate claim 42.

Applicant requests withdrawal of the rejection of claim 42 under 35 U.S.C. §102(e). In addition, Applicant requests withdrawal of the rejection of claims 43-46 which depend from claim 42 and are not anticipated by Rubsamen et al for at least the same reasons as claim 42.

In addition, independent claim 47 is also not anticipated by Rubsamen et al. Claim 47 is to a device for delivering an aerosolized active agent to the lungs of a human patient, said device comprising, inter alia, means for limiting an inspiratory flow rate to less than 17 liters per minute. Rubsamen et al does not disclose a means for limiting an inspiratory flow rate to less than 17 liters per minute. Accordingly,

Rubsamen et al does not anticipate claim 47.

Applicant requests withdrawal of the rejection of claim 47 under 35 U.S.C. §102(e). In addition, Applicant requests withdrawal of the rejection of claims 48-52 which depend from claim 47 and are not anticipated by Rubsamen et al for at least the same reasons as claim 47.

Conclusion

The claims are allowable for the reasons given above. Thus, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

JANAH & ASSOCIATES

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